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41. Research Within the North Dakota Department of Human Services

41-01. North Dakota Department of Human Services' Institutional Review Board

41-01-01. Forward

All prospective projects that pertain to research and human subjects as defined in this chapter and in 45 CFR 46, that involve DHS clients, staff, or data, must be reviewed by the North Dakota Department of Human Services' Institutional Review Board (DHS IRB). Internal data analysis undertaken exclusively for purposes of DHS needs assessment, program planning, program evaluation, or other administrative requirements is exempt from need for DHS IRB review. The DHS IRB will make the final decision regarding the need for IRB review on a case-by-case basis.

A DHS IRB application must be submitted and the project must be approved by the DHS IRB before any recruitment of subjects or data collection can begin.

41-01-05. Definitions as Used in this Manual

"Ad hoc committee" means a temporary committee comprised of IRB and/or non-IRB members to perform a specific function.

"Ad hoc committee member" means a selected individual who is a nonvoting, temporary member of the IRB for a specific purpose (e.g., assist in the review of a research proposal).

"Adverse event" means an unintended, but not necessarily unexpected, result of therapy or other intervention that is unpleasant or dangerous.

"Approval" means that the proposal, application, informed consent, and other submitted materials are reviewed and found acceptable by the IRB.

"Assent" is an affirmative agreement to participate in research. Mere failure to object should not be construed as assent.

"Belmont Report" is a statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

"Bona Fide" means to act in good faith.

"Child/Minor" is a person who has not attained the legal age for consent to treatments or procedures involved in the research.

"Cognitively impaired" means having a disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished.

"Continual review" means research that has been approved will undergo review until the completion or termination of the research, including scheduled continual reviews of research that will occur at least annually.

"Data" means information that is collected for analysis or used to reason or make a decision.

"Embryo" means the early stages of a developing organism, broadly used to refer to stages immediately following fertilization of an egg through implantation and very early pregnancy (i.e., from conception to the eighth week of pregnancy).

"Expedited review" means that research activities may be exempt from the policy if human subject involvement is limited to one of the listed scenarios, including studies involving the collection or study of existing data when those data either are publicly available or are not personally identifiable.

"Fetus" means the product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant [45 CFR §46.203(c)]. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development.

"Informed consent" is the knowing, legally effective consent of any individual or the individual's legally authorized representative.

"Inquiry" means information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

"Investigation" means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

"Institutional Review Board (IRB)" is a committee formed to ensure the protection of human subjects in research.

"Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Misconduct" or "misconduct in science" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

"Principal Investigator" is the individual with primary responsibility for the design and conduct of a research project.

"Prisoner" means an individual involuntarily confined in a penal institution.

"Protocol" is the formal design or plan of an experiment or research activity.

"Quorum" means the minimal number of members of the IRB, always a majority, who must be present or present via live video or audio technology, to conduct committee functions.

"Recuse" means to disqualify oneself from participation in a decision on grounds such as prejudice or personal involvement.

"Research" means studies undertaken to contribute to the body of generalizable knowledge.

"Secondary data analysis" is the re-analysis of data that has been previously collected and already exists.

41-01-10. DHS IRB Membership Policy

41-01-10-01. Membership

Membership is comprised of twelve members appointed by the Executive Director of the Department of Human Services for staggered three-year terms. The Chair, legal representative, management representative of the division from Mental Health and Substance Abuse, and medical representative members are assigned by the Executive Director. They are permanent members until they resign their role from the committee, they resign their employment from DHS, or they are removed by the Executive Director.

The expiring non-permanent committee memberships conclude only when the Executive Director appoints a new member.

New members are established through recommendation of the non-expiring Board members to the Executive Director of the Department of Human Services for appointment to vacant or vacating positions. Members may be re-appointed to consecutive terms. Removal of a member is by a majority vote of the board or by the Executive Director. Appeals of removal from the board by majority vote of the board are given to the Executive Director of the Department of Human Services with no further recourse for review.

In the event that an IRB member is unable to attend three out of four consecutive meetings of the IRB, or is not able to meet task deadlines set by IRB policy, it is the prerogative of the Chair to request that member's resignation from the IRB and the appointment of a successor by the Executive Director.

41-01-10-01-01. Representation of Membership

Recommendation for membership must incorporate the following structure:

- An attorney from the Department of Human Services' Legal Advisory Unit
- Two members from regional Human Service Centers
- A staff member from a state-operated residential treatment center
- A staff member of the Research and Statistics Division of DHS
- A physician of DHS
- A psychologist of DHS
- The remaining representation will come from other Department of Human Services' divisions.

41-01-10-01-05. Consumer Representation

- IRB membership must include a representative of at least one consumer advocacy organization.

Additional specialists may be asked by the Chair to assist the Board for the particular expertise or perspective needed for appropriate consideration of a given proposal or issue. Any such ad hoc members will serve in an advisory capacity and will not have voting privileges.

41-01-10-05. Quorum

The IRB performs full committee functions only when a quorum of six members, including at least one nonscientific member, is physically present, or via live video or audio technology. Decisions may also be submitted through e-mail to conclude business initiated while in session requiring final approval by the membership.

41-01-10-10. Conflict of Interest

Members must recuse themselves from consideration of proposals by researchers for whom there is a direct working or personal relationship. This includes administrative or clinical relationships in the workplace. Review of proposals from the same organizational unit is cause to recuse from the decision. Such members are encouraged to contribute to discussion, but refrain from the decision process. Where there is a direct personal relationship, the member will recuse from the decision. Where conflict of interest is uncertain, discussion by the Board can be used to provide guidance.

41-01-10-15. Specialized Board-member Roles

A proposal submitted for review may have an individual assigned by the Chair to facilitate the primary researcher in completing the review process successfully. The Facilitator is recused from the decision process regarding the specific proposal, while being available to advise the researcher for design and clarity improvements.

41-01-15. DHS IRB Regulations and Procedures

41-01-15-01. Meetings

The DHS IRB will meet as needed. The IRB performs full committee functions only when a quorum is present. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Meeting minutes must include attendance at each meeting; actions taken by the IRB; the vote on actions taken (including the number of members voting for, against, and abstaining); the basis for requiring changes in or disapproving research, and; a written summary of the discussion of controverted issues and their resolution. Votes will be taken and recorded for actions regarding: research proposals, IRB minutes, and expenditures.

41-01-15-05. Record Keeping

Records of all submitted proposals (approved, remanded for revision, or rejected) will be kept in an electronic database. In addition, hard-copies of all proposal materials (e.g., application, informed consent forms, original submitted proposal, and data-gathering instruments), e-mails and/or letters that contain communication between the Principal Investigator and IRB members, and any other applicable documentation will be kept in individual proposal files.

41-01-15-05-01. Electronic Database

Information that is entered into the database includes but is not limited to: the proposal number, submission date of the proposal, title of the study, purpose of the study, name of the Principal Investigator with contact information, Co-Principal Investigators with contact information, type of review (i.e., full board or expedited), IRB members assigned to the expedited review (if applicable), date expedited review was assigned (if applicable), date of initial review, outcome of review, next date of continual review, informed consent expiration date (if applicable), "Research Progress Report" notes, "Change in Procedure or Principal Investigator Application" notes, research closure date, record disposal date, abstract of results from the study, date posted to the DHS IRB website, and other notes.

All IRB records will be retained for at least three years; and records pertaining to research that is conducted will be retained for three years after completion of the research.

41-01-15-10. DHS IRB Review Process

The Principal Investigator must submit, to the DHS IRB Chair, the appropriate application materials along with the research proposal, informed consent forms, and any supporting documents. The Social/Behavioral application form will be used as the default application. The Social/Behavioral application is to be used in all instances where any medical procedures/devices and/or drugs will *not* be used. The Medical application is to be used only when there will be medical procedures/devices and/or drugs used in the study. If the proposed research has been reviewed by another IRB, documentation of approval by that IRB must be submitted with the application. If the proposed research is currently under review by another IRB, documentation of approval by that IRB will be required prior to final approval by the DHS IRB.

IRB members will be informed that a new research proposal has been submitted. The IRB members assigned to review the proposal will be sent copies of the original proposal along with any other materials submitted by the Principal Investigator. Reviewers will also be sent three Informed Consent checklists, a document with categories of research that may be reviewed through an expedited review procedure, and an "IRB Protocol Review Standards" checklist. The "IRB Protocol Review Standards" checklist must be signed and dated by the Reviewers and returned to the IRB Chair for review. The protocol review checklist will then be filed with the other materials from that proposal.

After the research proposal is reviewed by the IRB, the Principal Investigator will be notified by letter whether the proposal is approved, remanded with revisions, or disapproved.

If the proposal is approved, the entities associated with the study will be contacted to inform them that a proposal has been submitted. The associated entities are to be notified of the outcome of the review and when the study is either terminated or completed. The associated entities will be sent a copy of the final report and will be advised that an abstract of results of the study will be posted on the DHS IRB website.

41-01-15-10-01. Full Board Review Process

In the case of a full board review, the research proposal will be reviewed by all IRB members. In order for the proposal to be approved, the majority of the board must vote in favor of its approval. There is a 30 workday policy for full-board reviews, unless otherwise approved for additional review time by the DHS IRB Chair.

41-01-15-10-05. Expedited Review Process

The DHS IRB Chair will decide whether the proposal will require a full board review or will qualify for an expedited review. The decision of whether a proposal requires full board review or qualifies for an expedited review will be contingent upon whether the proposal meets the criteria for minimal risk as indicated in the Code of Federal Regulations. Proposed research that qualifies for an expedited review will be reviewed by the IRB Chair or a designated voting member or group of voting members rather than by the entire IRB. There is a 14 workday policy for expedited reviews, unless otherwise approved for additional review time by the DHS IRB Chair. Following the review and approval process, IRB members will be informed of all expedited reviews and the outcomes of those reviews on or before the next convened meeting.

41-01-15-15. Continual Review

Research that is approved will be in a continual review process. Following initial approval of research, there will be scheduled continual reviews of that research that will occur at least annually. Reviews may be required more often than annually if the IRB determines the protocol to be high-risk or a protocol with a high-risk potential benefit ratio. Research may be subject to unscheduled continual reviews when the IRB deems appropriate.

When research proposals are approved or disapproved, when research is due for a continual review, and in other appropriate instances, written letters will be the form of communication. When available, e-mail will be the primary form of communication between the IRB and the Principal Investigator.

The Principal Investigator is required to submit a "Change in Procedure or Principal Investigator" form before there is any change in protocol. Those changes are subject to either full board review or expedited review. The department(s) associated with the study must be notified of those changes. Proposed changes may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant. If emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject. Such emergency care may not be claimed as research, nor may any data regarding such care be included n any report of a prospectively conceived research activity.

Four to six weeks before each scheduled continual review, the Principal Investigator will be notified by letter that the research is due for a continual review. For each scheduled continual review, the Principal Investigator must submit a "Research Progress Report" on or before the continual review due date. Extensions will be granted on a case-by-case basis by the Chair. The continual review of the research may be subject to a full board review or an expedited review. A "Research Progress Report" must also be submitted if the Principal Investigator decides to terminate the study or at the completion of the study as a final report. At the completion of a study, the Principal Investigator must submit, along with the final progress report, a copy of their final project. The North Dakota Department of Human Services will have the right to utilize and disseminate the data that was gathered and analyzed.

In the event that the Principal Investigator is requested to share the data generated by his/her study at a later time by a *bona fide* researcher, the Principal Investigator may only release data that has either had identifying information deleted or has been encrypted so as to prevent the connection of identity with data.

Certain projects may require verification from sources other than the investigator that no material changes have occurred since previous IRB review. These projects will be identified at the discretion of the IRB and may include one or more of the following: (i) randomly selected projects; (ii) complex projects involving unusual levels or types of risk to subjects; (iii) projects conducted by investigators who previously have failed to comply with the requirements of HHS regulations or the requirements or determinations of the IRB; and (iv) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports of from other sources).

If review of a project indicates the possibility of scientific misconduct, then Section 41-05 below becomes applicable. If the ensuing investigation determines that scientific misconduct has occurred, or if the research has not complied with the requirements or determinations of the IRB, the IRB approval of the project may be suspended or terminated. Suspension or termination of IRB approval will be promptly reported to appropriate institutional officials.

41-01-15-20. Informed Consent

Except as specifically allowed in 45 CFR § 46, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Informed consent, whether oral or written, may not include language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

To obtain informed consent, the human subject involved in research must be provided with the following information:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that records may possibly be inspected.

6. For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject; and

8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

If participation in a study offers minimal risk or greater, participants must be informed, in the informed consent, about details of the research study in which they will participate. The informed consent must be signed by the participant to indicate comprehension of the extent to which he/she will participate. Research participants must be provided with a copy of the signed informed consent.

41-01-15-20-01. Waiver of Informed Consent

The Common Rule codified in 45 CFR § 46.116(d) specifies that an IRB can alter or waive the requirement to obtain informed consent if it finds and documents that the research involves no more than minimal risk to the subjects, the waiver or alteration will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If the Principal Investigator requests a waiver of informed consent, they must complete the "Request for Waivers of Informed Consent" form and submit the form with the application. A waiver of informed consent may be granted if the IRB decides that *written* informed consent is not needed (e.g., Internet or phone surveys). In this case, the Principal Investigator provides the informed consent form to the participant but no signature is required. The other instance in which a waiver of informed consent may be granted is when *no* informed consent is necessary (e.g., secondary data analysis). If the Principal Investigator requests a waiver of informed consent, they cannot proceed with the study without using informed consent forms until the Principal Investigator is notified by the IRB.

The Informed Consent form must have an Approval Date and an Expiration Date approved by the DHS IRB. It is the Principal Investigator's responsibility to obtain re-consent from the research participants when informed consent expires.

If the Principal Investigator proposes to videotape any part of the study in which the research participants are involved, the Principal Investigator must present the "Consent for Videotaping" form in addition to the informed consent form(s).

41-01-15-25. Certificate of Confidentiality

The IRB may decide that due to sensitive information, the Principal Investigator must request a Certificate of Confidentiality.

A Certificate of Confidentiality is a grant for additional assurance/protection of confidentiality, which the Principal Investigator must apply for through the National Institute of Health.

A Certificate of Confidentiality is additional privacy protection for both subjects and researchers. The Certificate protects the subjects' identities and research data if private information is ever sought by law enforcement and sometimes under subpoena. The Certificate of Confidentiality also protects the researcher from incarceration for not cooperating to reveal identities or research data.

Certificates of Confidentiality are given only under circumstances where the research is of a sensitive nature and where the protection is judged necessary to achieve the research objectives. Protection is available for: direct federal activities; federally-funded activities, and; research in the United States that has no federal funding. "Sensitive" research information is defined as falling into any of the following categories:

1. Information relating to sexual attitudes, preferences, or practices;

2. Information relating to the use of alcohol, drugs or other addictive products;

3. Information pertaining to illegal conduct;

4. Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;

5. Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;

6. Information pertaining to an individual's psychological well being or mental health; and

7. Genetic information.

41-01-15-30. Special Subject Populations

It is the policy of the North Dakota Department of Human Services not to discriminate against any individual on the basis of race, color, religion, national origin, sex, sexual orientation, marital status, age, disability, or veteran's status. The department will treat individuals equally and will provide reasonable accommodations when necessary. The IRB will expect proposed research designs and procedures to be consistent with this policy.

41-01-15-30-01. Children and Wards

In a case in which the research participants are children or minors, the assent of the child or minor is required along with the permission of the parent(s). The parent's permission supplants the consent of the participant (child).

While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent to or dissent from participation. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research does not involve interventions likely to be of benefit to the subjects and the children can comprehend and appreciate what it means to be a volunteer for the benefit of others. The IRB will determine for each protocol - depending on such factors as the nature of the research and the age, status, and condition of the proposed subjects - whether all or some of the children are capable of assenting to participation. Where appropriate, the IRB may choose to review on a case-by-case basis whether assent should be sought from given individual subjects. Assent does not need to be sought from children starting at a specific age, but their assent should be sought when, in the judgment of the IRB, the children are capable of providing their assent. The IRB will take into account the ages, maturity, and psychological state of the children involved. The proposed research procedures should be explained to the child orally by the Principal Investigator in terms that the child can understand, in addition to having the child signing an assent form.

The IRB will require, for each child who is a ward, the appointment of an advocate in addition to anyone acting as a guardian on the child's behalf.

41-01-15-30-05. Women and Minorities

So that research findings may benefit *all* persons, the DHS IRB policy regarding the inclusion of women and minorities in the research subject population reflects that of the National Institutes of Health (NIH) policy. Specifically, the NIH policy states:

Applications for grants and cooperative agreements that involve human subjects are required to include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy applies to all research involving human subjects and human materials, and applies to males and females of all ages. If one gender and/or minorities are excluded or are inadequately represented in this research, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided. The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. Assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH.recognize[s] that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (**i.e**., American Indians or Alaskan Natives, Asians or Pacific Islanders, Blacks, Hispanics). Provide the rationale for studies on single minority population groups.

Applications for support of research involving human subjects must employ a study design with gender and/or minority representation (by age distribution, risk factors, incidence/prevalence, etc.) appropriate to the scientific objectives of the research. It is not an automatic requirement for the study design to provide statistical

power to answer the questions posed for men and women and racial/ethnic groups separately; however, whenever there are scientific reasons to anticipate differences between men and women, and racial/ethnic groups, with regard to the hypothesis under investigation, applicants should include an evaluation of these gender and minority group differences in the proposed study.

If adequate inclusion of one gender and/or minorities is impossible or inappropriate with respect to the purpose of the research because of the health of the subjects, or other reasons, or if in the only study population available, there is a disproportionate representation of one gender or minority/majority group, the rationale for the study population must be well explained and justified.

41-01-15-30-10. Pregnant Women

Research involving women who are pregnant or where there is a possibility of pregnancy, will receive special attention from the IRB because of the additional health concerns during pregnancy and to prevent unnecessary risk to the fetus. Studies in which women of child-bearing potential are possible subjects may inadvertently include pregnant women.

When appropriate, informed consent forms should include a "statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable." In a case where research does involve pregnant women, the IRB will decide whether the consent of the father is necessary. DHHS regulations require the consent of both the mother and the father except in the following circumstances: (1) the purpose of the research is to meet the health needs of the mother; (2) the father's identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape. There are no regulations involving lactating women. In this circumstance, the IRB will focus on the safety of the nursing infant.

41-01-15-30-15. Prisoners

When the IRB reviews a protocol in which a prisoner is a subject, the IRB must insure that a majority of the Board (exclusive of prisoner members) will have no association with the prison(s) involved, apart from their membership on the Board. Additionally, at least one member of the Board will be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

When the IRB reviews a protocol in which a prisoner is a subject, it will make and document the following seven additional findings:

1. The research under review represents one of the categories of research permissible under Section 45 CFR § 46.306(a)(2);

2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners;

5. The information is presented in language, which is understandable to the subject population;

6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

7. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

The IRB will measure minimal risk of research involving prisoners as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. When the IRB reviews a research proposal involving prisoners, it will use one of the following categories on which it will base its decision for approval or disapproval:

1. Research on the possible causes, effects, and processes of incarceration, and of criminal behavior provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

2. Research on prisons as institutional structures or of prisoners as incarcerated persons provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject.

41-01-15-30-20. Cognitively Impaired Persons

Unlike research involving children, prisoners, and fetuses, no additional DHHS regulations govern research involving people who are cognitively impaired. The regulations for cognitively impaired persons should resemble those that govern research involving children.

41-01-15-30-25. Elderly/Aged Persons

There are no specific regulations governing research with elderly subjects. The two circumstances in which the elderly population requires special protections are cognitive impairment and institutionalization. Under these two circumstances, the regulations apply to the elderly as with any other, non-elderly subject in the same circumstances. Further, there is no age at which prospective subjects may not participate in research.

41-01-15-35. Adverse Events

Any adverse events that occur during a study must be reported to the North Dakota Department of Human Services' Risk Manager, who will investigate the matter. The Principal Investigator must complete and submit either an "Off-site Adverse Event Report" or an "On-site Adverse Event Report." The adverse event must be reported to the Risk Manager within three days of Principal Investigator's knowledge of the incident.

41-05. Reporting of Possible Misconduct in Science

41-05-01. Preface

Subpart A to 42 CFR Part 50 of the federal Public Health Service (PHS) establishes a requirement that recipients of PHS funds utilized for research, research training, or related activities have in place policies to deal with reporting of possible misconduct in science. The following policy is established within the North Dakota Department of Human Services to allow compliance with the federal rule.

41-05-05. Reporting of Allegations of Scientific Misconduct

Reports of suspected scientific misconduct relating to PHS funds received by the department should be reported directly to the Executive Director. In the event of suspected scientific misconduct involving the Executive Director, the report must be filed directly with the state Attorney General.

41-05-10. Inquiry into Allegations of Suspected Scientific Misconduct

Inquiry into an allegation of scientific misconduct involving PHS funds received by the department must begin immediately upon receipt of the report. Inquiry regarding an allegation must be completed within 60 calendar days from the date of receipt of the allegation, including preparation of a written report. Documentation of the inquiry, including the final report, sufficiently detailed to permit a later assessment of the reasons for determining an investigation was not warranted, must be retained for a minimum of three years within the department, and must be made available to authorized personnel from the federal Department of Health and Human Services upon request. The written report must state what evidence was reviewed, summarize relevant interviews, and include the conclusions of the inquiry. An individual against whom an allegation was made must be given a copy of the report of inquiry. If the individual comments on the report, the comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry must include documentation of the reasons for exceeding the 60-day period.

The Director, the Office of Research Integrity (ORI), must be notified, in accordance with 41-05-30 when, on the basis of an initial inquiry, the department determines an investigation is warranted or prior to the decision to initiate an investigation if the conditions listed in 41-05-30-10 exist.

If there is any reasonable indication of possible criminal conduct, ORI must be notified within 24 hours.

41-05-15. Investigations

If findings from the initial inquiry provide sufficient basis for conducting an investigation, the investigation must be initiated within 30 days of completion of the inquiry. The investigation normally includes examination of all documentation, including relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews must be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who may have information regarding key aspects of the allegations. Complete summaries of these interviews must be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

The investigation must be completed within 120 calendar days. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to ORI. If the individual can be identified, the person who raised the allegation must be provided with the portion of the report that addresses the individual's role and opinion in the investigation.

If the department plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under this chapter, a report of the planned termination, including a description of the reasons for the termination, must be made to ORI, which may decide whether further investigation must be undertaken.

41-05-20. Expertise – Conflict of Interest

An individual chosen to participate in inquiry or investigation of an allegation of scientific misconduct shall have necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence and must be carefully chosen to avoid real or apparent conflicts of interest.

41-05-25. Confidentiality

To the maximum possible extent, an individual affected by an allegation of scientific misconduct must be afforded confidential treatment of the inquiry and investigation, and must be provided with an opportunity to comment on an allegation and findings of the inquiry and the investigation.

41-05-30. Notification and Reporting Concerning Investigations

41-05-30-01. Reporting to ORI

The department's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person or persons against whom an allegation has been made, the general nature of the allegation, and the PHS application or grant number involved. Information provided through the notification must be held in confidence to the extent permitted by law and must not be disclosed as part of the peer review and advisory committee review processes.

The final report submitted to ORI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual found to have engaged in misconduct, as well as a description of any sanctions taken by the department.

41-05-30-05. Delays in Investigation

If the department determines that it may not be able to complete the investigation in 120 days, it may submit to ORI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. If the request is granted, the department shall file periodic progress reports if requested by ORI.

41-05-30-10. Special Reports

The department shall notify ORI if it ascertains, at any stage of the inquiry or investigation, that:

1. There is an immediate health hazard involved;

2. There is an immediate need to protect federal funds or equipment;

3. There is an immediate need to protect the interests of any person making allegations or any individual who is the subject of allegations as well as the individual's co-investigators and associates, if any;

4. It is probable that the alleged incident is going to be reported publicly; or

5. There is a reasonable indication of possible criminal violation.

41-05-35. Protection of Federal Funds

During an inquiry or investigation relating to alleged scientific misconduct, the Fiscal Administration Division of the department shall take appropriate interim actions to protect the federal funds and ensure that the purposes of the federal financial assistance are being carried out. The department shall promptly advise ORI of any developments during the course of an investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual under investigation or that PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.

41-05-40. Unconfirmed Allegations

The department shall make every reasonable effort to restore the reputation of a person alleged to have engaged in misconduct when an allegation is not confirmed.

41-05-45. Protection of Reporters

To the maximum extent reasonably possible, the position and reputation of the person who, in good faith, makes an allegation of scientific misconduct, and the person against whom an allegation of misconduct is not confirmed, must be protected.

41-05-50. Sanctions

The department, with advice from the Attorney General's Office, shall impose on an individual when an allegation of misconduct has been substantiated. ORI must be provided with a written report of the final outcome of investigation, including a thorough description of the investigative process and the findings.

41-05-55. Notification of Staff

The department shall inform its scientific and administrative staff of this policy and of the importance of compliance with the policy.

41-10. Fee Policy

The fee for the original IRB application will be $1,000 for each proposal and $500 for each continual review. Exceptions may be made for students and for researchers who are employed or contracted by the Department of Human Services, and performing research within their scope of duties with DHS. Others for whom the fees may constitute a financial hardship will be considered by the IRB for exemption of fees on a case-by-case basis. A request for waiver of fee must be submitted and approved by the IRB prior to or at the time of application. Monies generated from these fees will be applied to IRB training and administrative costs.

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